UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,254	03/10/2004	Curtis Wright	Y2428-00014	9103

42109 7590 09/18/2007

DUANE MORRIS LLP
PATENT DEPARTMENT
1540 BROADWAY
NEW YORK, NY 10036-4086

EXAMINER	
MONSHIPOURI, MARYAM	
ART UNIT	**PAPER NUMBER**
1656	

MAIL DATE	DELIVERY MODE
09/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,254	WRIGHT ET AL.	
	Examiner	Art Unit	
	Maryam Monshipouri	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) 9-30 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's response to restriction requirement of 5/24/2007 is acknowledged. Applicant elected Group I (claims 1-8) with traverse. Claims 9-30 are hereby withdrawn as drawn to non-elected invention.

In traversal of restriction requirement applicant argues that a search for Group I invention will also yield the prior art, if any, of Groups II-IV. Therefore, examining all inventions would not impose an undue burden of searching on the examiner and hence, all inventions should be examined together.

This argument was fully considered but was found unpersuasive because a search for Group I invention would not necessarily reveal relevant art to inventions of Groups II-IV since as indicated previously, the limitations, end-points and steps of each listed invention is different. It is true that there may be some overlap between the searches required for inventions of Groups I-IV, but said searches certainly are **not coextensive**. Therefore in contrast to applicant's view rejoinder of all listed inventions does impose and undue burden of searching on the examiner.

In conclusion, for the response provided here, in addition to those provided previously, restriction is maintained and is hereby made **Final**.

DETAILED ACTION

Claims 1-8 are under examination on the merits. Claims 9-30 are withdrawn as drawn to non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Leppert (Nowotwory, 51(3), 31-38, 1996) in view of current pain management methods and regimens. Leppert teaches a dosage regimen comprising administering to patient an oral controlled release and/or subcutaneous tramadol wherein the patients were treated with a total of 150-600 mg of tramadol everyday for 28 days (see page 259), wherein said drug was usually administered in the forms of drops or tablets. Such dosages in general meet the limitations of claim 1 (and its dependent claims) because 125mg mentioned in claim 1 is very close to 150 mg of Leppert, in pain intensity (VAS) scale, which is the best indicator of drug efficacy, and the treatment period of Leppert of up to 28 days meets the 8-21 (4+4+1 to 10+10+1) day treatment (see claim 1) period of this invention. However, since Leppert does not spell out the exact doses for the exact periods indicated in claim 1 (and its dependent claims 2-8) it is believed that if Leppert is not anticipatory to this invention it at least renders it obvious, in view of current pain management methods and regimens.

Current pain management methods and regimens teach that depending on the location and intensity of pain in a patient, the period of treatment, the amount and chemical structure (i.e. salt form, isomer etc.) of analgesic (such as tramadol) administered may be optimized. Said methods and regimens also teach that one must

start with smaller doses of analgesics and gradually increase their amount, stepwise, in order to give patient time to adapt to the drug effects (and side effects), as well as arrive at some pain control.

It would have been obvious to one of ordinary skill in the art to start with the tramadol administration method of Leppert and optimize its administration (both controlled release or immediate release) in terms of dosage, the type of tramadol (or salts thereof such as tramadol hydrochloride, or tramadol isomers etc.) and duration of treatment etc. to obtain the best pain management regimen and treatment methods.

One of ordinary skill in the art is motivated in optimizing the tramadol administration method (regimen) of Leppert according to current pain management methods and regimens because such optimal pain management regimens will result in patient's improvement in well being, quality of life and emotional state, rendering the invention obvious.

Finally, one of ordinary skill in the art has a reasonable expectation of success in optimizing the dosage regimen of Leppert according to current pain management methods and regimens because such regimens optimization methods are merely routine in the art.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on Tues.-Fri, everyday from 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleene Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. Monshi/
Maryam Monshipouri Ph.D.
Primary Examiner

***